DOM04 – Practices for Validating Technical Procedures

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1. Background

1.1. These practices provide direction for validating new technical procedures prior to those procedures being introduced into casework in the Department of Forensic Sciences (DFS) Forensic Science Laboratory (FSL). Validation is the process by which the scientific community acquires the information necessary to assess a procedure's capability for obtaining reliable and reproducible results. These practices also satisfy the requirements of the *FSL Quality Assurance Manual* and the accreditation program under ISO/IEC 17025:2005 standards and supplemental standards.

2. Definitions

2.1. For purposes of this document, the following terms shall have the designated meanings:

DFS: Department of Forensic Sciences

DOM: Departmental Operations Manual

FSL: Forensic Science Laboratory

Validation: The process of performing a set of experiments that establish the efficacy and reliability of a technique or procedure or modification thereof.

3. Scope

3.1. These practices apply to new technical procedures or methods, whether developed internally or externally, that pertain to casework.

4. Responsibilities

4.1. The Individual/Group performing the validation will:

4.1.1. Appropriately document and retain results of validation and modification studies.

4.1.2. Retain the documentation of the review process.

4.1.3. Prepare a standard operating procedure(s) *for casework.*

4.2. The Laboratory Manager, Technical Leader, and/or FSL Director will:

4.2.1. Review the validation process and results before the procedure is used in the *FSL*.

4.2.2. Document this review after all concerns/issues have been addressed between the individual/group preparing the validation documentation and the technical reviewer(s).

4.2.3. Approve all validations deeming a procedure ready and appropriate for casework.

5. Practices

5.1. Validation is the acquisition of test data using the proposed methods and procedures to demonstrate that the expected outcome is reproducible and achieves reliable results. All technical procedures must be validated in the FSL prior to use for forensic examinations. Prior to beginning a validation study, a plan of action will be prepared and documented by the person/group tasked with the validation. The Laboratory Manager, Technical Leader and /or FSL Director will review and approve the plan of action for the proposed validation study.

5.2. Each FSL unit will define and/or reference the requirements for a discipline-specific validation study, if applicable and where appropriate. The validation study will determine:

5.2.1. The limitations of the procedure.

5.2.2. Conditions under which reliable results can be obtained.

5.2.3. Critical aspects of the procedure that must be controlled and monitored.

5.2.4. The scope and accuracy of the procedure necessary to meet the needs of the given application.

5.3. When validating a novel or existing procedure, known samples must be used. Prior to applying a novel or existing procedure to the examination of evidence, documentation must demonstrate that the procedure performs as expected, or with modification performs as expected, in the FSL.

5.4. If internally validated procedures are used in a new environment, such as a satellite laboratory, appropriate internal validation studies must be conducted and documented for that site-specific environment ensuring consistency.

5.5. Validation Review and Documentation

5.5.1. A technical reviewer will evaluate the validation study before use of the procedure in the FSL. A technical reviewer is an individual who possesses the knowledge and/or experience on the corresponding scientific application. The technical reviewer(s) will document agreement with the validation results with a signature and date of review.

5.5.2. Upon completion of the technical review, a standard operating procedure will be written for the validated technical method/procedure for use in forensic examinations. The standard operating procedure must be approved prior to use for forensic examinations (*DOM02 – Practices for Document Control*).

5.6. Competency Tests

5.6.1. Each analyst who will apply the validated technical method/procedure to casework must successfully complete a competency test prior to use on casework. This test will demonstrate that the analyst can accurately perform the technical method/procedure using the approved standard operating procedure. The competency test file and its associated results will be maintained with the Deputy Director of Quality Assurance and/or the unit-specific Quality Assurance Liaison.

6. Documentation

6.1. The following records will be generated and permanently retained by the applicable unit in the laboratory:

6.1.1. Validation Notes

6.1.2. Validation Report

6.1.3. Standard Operating Procedures

7. References

7.1. ISO/IEC 17025 – General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland (current revision).

7.2. ASCLD/LAB-International® Supplemental Requirements for the Accreditation of Forensic Science Testing and Calibration Laboratories, American Society of Crime Laboratory Directors/Laboratory Accreditation Board, Garner, NC (current revision).

7.3. Quality Assurance Standards for Forensic DNA Testing Laboratories, Federal Bureau of Investigation, (current revision).

7.4. Forensic Science Laboratory Quality Assurance Manual (current revision)

7.5. Unit-specific Quality Assurance Manual (current revision)